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510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the
GammaMed plus 3/24
High Dose Rate (HDR) Remote Afterloader

1. Submitter:

Varian Medical Systems
3100 Hansen Way M/S E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
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Fax: (650) 842-5040
Email: vy.tran@varian.com
Date: September 22, 2003

2. Device Name:

GammaMed plus 3/24 High Dose Rate (HDR) Remote Afterloader
Classification Name: System, Applicator, Radionuclide, Remote-Controlled
Common/Usual Name: GammaMed plus 3/24 HDR Remote afterloader
Proprietary Name: GammaMed plus 3/24 HDR Remote afterloader

3. Equivalent Device:

GammaMed plus HDR Remote Afterloader, K983436

4. Device Description:

The GammaMed*plus* 3/24 is a remote afterloading system used to deliver a radioactive source for use in high-dose rate brachytherapy. The GammaMed 3/24 is loaded with sources no greater than 10 curies. The GammaMed*plus* 3/24 differs from its predicate device in that it has only five treatment channels.

The GammaMed*plus* 3/24 consists of a remote afterloading device, an optional transportable trolley, and operator console. The GammaMed*plus* 3/24 remote afterloading device contains a radioactive source, a shielded safe in which to park the source when not in use, motors to drive the source, an indexer to determine the treatment channel for the source, position encoders for the source, electronic control circuit boards, a battery pack for backup power, and a power supply.

The radioactive material is sealed inside a stainless steel source capsule. The source capsule is attached to the source cable to form the source assembly. The source cable is also fabricated from stainless steel. The source assembly is housed inside a source tube. The source tube assembly is surrounded by tungsten metal which is used as shielding material. The radiation dose rate at a distance of one meter from the GammaMed*plus* 3/24 afterloading device when containing a source of the maximum activity is less than 3μGy/h.

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An electro-mechanical key lock is provided to prevent actuation of the source when the afterloading device is not in use.

The source guide tubes attach to the afterloading device by means of a special quick connector. The source may be exposed through a particular channel only if the source guide tube is properly attached to this channel. The applicators to be employed in a particular treatment are connected to the GammaMed*plus* indexer by way of the source guide tubes.

The afterloading device also contains a simulation ("dummy") source assembly. This simulation source assembly is identical to the actual source assembly except that it does not contain radioactive material. The simulation source makes it possible to test the condition and location of the source guide tube and the applicators and their connections before carrying out the actual treatment. The device is equipped with 5 access channels, through which the single iridium¹⁹² source can be manipulated. The source exit port can be raised or lowered into a position that is optimal in relation to the particular patient. The position of the exit port of the afterloading device can be varied from 900 millimeters (34 inches) above the floor to 1800 millimeters (51 inches) above the floor. A wide range of flexible and rigid applicators is available for a wide variety of brachytherapy techniques.

The afterloading device is equipped with an emergency hand crank to permit the emergency retraction of the source. The hand crank is a "one way" hand crank, which allows only retraction of the source. It is not possible to expose the source using this hand crank.

The afterloading device can be installed onto a trolley for transportation. The GammaMed trolley consists of a rectangular chassis with four large casters for easy movement of the equipment. It has a manually operated brake that reliably maintains its position during treatment.

5. Statement of Intended Use:

The GammaMed*plus* 3/24 is a remotely controlled afterloading brachytherapy device used to apply a radionuclide source into the body or to the surface of the body for radiation therapy. The GammaMed*plus* 3/24 may optionally be configured as a transportable device.

6. Comparison to substantially equivalent devices:

Features / Products		GAMMAMED plus	GAMMAMED plus 3/24
Device	FDA clearance	K983436	Pending
	Base Area	57.5 cm x 51 cm	57.5 cm x 51 cm
	Height	105cm-145cm	105cm-145cm
	Adjustable height position measured in the center of the indexer	90cm-130cm	90cm-130cm
	Weight	130kg	130kg
	Transportable(USDOT-7A; Type A)	Yes	Yes
	Power Supply	115 V 60 Hz	115V 60 Hz
	Mobile	Yes	Yes
	HDR	Yes	Yes
	Number of Channels	24	5
	Features / Products	GAMMAMED plus	GAMMAMED plus 3/24

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Features / Products		GAMMAMED plus	GAMMAMED plus 3/24
	Shielding	Tungsten	Tungsten
Device: Cont.	Maximum shielding activity	555 GBq /15 ci	555 GBq /15 ci
	Maximum treatment activity	370 GBq /10 ci	370 GBq /10 ci
	Maximum exposure rate at 1m. distance containing the maximum activity	0.3mrm/hr 3 uSv/hr	0.3mrem/hr 3 uSv/hr
	Dwell positions per each channel	60	60
	Area radiation monitor (integrated Geiger – Muller)	Yes	Yes
	Device Control Software	GammaWin	GammaWin
	Maintained treatment data during power failure (battery powered RAM)	Yes	Yes
	Simulator source	Yes	Yes
	Verification of channel length	Yes	Yes
	Verification of applicator connection	Yes	Yes
	Source positioning	Dixal to proximal	Dixal to proximal
	Maximum source position error over treatment length	0.35% referencing to 600 mm	0.35% referencing to 600 mm
	Emergency container for the source	Yes	Yes
	Response to emergency signal	Automatic source retraction	Automatic source retraction
	Emergency manual retraction	Yes	Yes
Source	Isotope	Ir-192	Ir-192
	Maximum activity	555 GBq /15 ci	555 GBq /15 ci
	Maximum treatment activity	370 GBq /10 ci	370 GBq /10 ci
	Capsule dimensions	4,52 x 0.9 mm	4,52 x 0.9 mm
	Active dimensions	3,5 x 0.6 mm	3,5 x 0.6 mm
	Source extension length	1300 mm	1300 mm
Operator Console	Operating console with Personal with Personal Computer and Printer	Yes	Yes
	Keyswitch control	Yes	Yes
	Operating voltage	24V from GammaMedplus	24V from GammaMedplus 3/24



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K031524
Trade/Device Name: GammaMed Plus 3/24
HDR Remote Afterloader
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled
radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: September 25, 2003
Received: September 29, 2003

Dear Mr. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

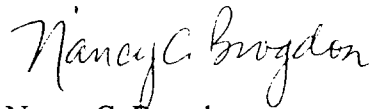
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031524
Device Name: GammaMed Model plus 3/24 HDR Remote afterloader

Indications For Use:

The GammaMed^{plus} 3/24 is a remotely controlled afterloading brachytherapy device used to apply a radionuclide source into the body or to the surface of the body for radiation therapy. The system is designed to provide a predetermined dose of radiation to tissue and organs by means of manipulating a radioactive source from a shielded position within in the device into a catheter, applicator, or needle, which has been placed within or on a patient. The remote afterloading device must be contained in a shielded facility during extension of the radioactive source. The GammaMed^{plus} 3/24 may optionally be configured as a transportable device.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David R. Lippman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031524

Prescription Use ✓